MAR 2 7 2003

K030859

510(k) Summary
for
[Product Name]

1. SPONSOR

Enamelite LLC
1800 Business Park Drive
Suite 406
Clarksville, TN 37040
Contact; Phillip Pitts, V.P. Products and Technology
Tel#-931-647-7171
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Date Prepared : March 14, 2003

2. Device Name

Proprietary Name:	Nova Ceramic Spray Glaze and Tru-Paque, Opaque Porcelain
Common/Usual Name:	Porcelain Powders
Classification Name:	Porcelain Powders

3. PREDICATE DEVICES

Leach and Dillon Shake and Spray Porcelain Powders – K895889

4. DEVICE DESCRIPTION

Ceramic Finishing Glaze (Nova Ceramic Spray Glaze). The Enamelite Nova Ceramic Spray Glaze is essentially identical to that used in the Leach and Dillon Shake n Spray powders. It is made of glass frit and is applied to dental restorations in an aerosolized uncontaminated form. Like all other porcelain powders, the Nova Ceramic Spray Glaze is only applied on dental laboratories. As with the parent Leach and

Dillon device, the Nova Ceramic Spray Glaze in an aerosol form decreases the in-process time of hand applied glazing methods while providing a substantially more even coating of glaze. Both the parent and modified devices allow the dental technician to apply glaze on either single or multiple units at one time. The Nova Ceramic Spray Glaze is used to construct restorations that fire at temperatures from 650° C to 930° C. Various types of porcelains that are compatible with Nova Glaze include porcelain-fused-to metal, pressed ceramic restorations and milled zircon restorations. The Nova Glaze enables the dental technician the ability to spray a glaze over unfired dental ceramic stains and over unfired add-on porcelains which some restorations may require to esthetically match the dental patient's natural teeth. This flexibility will make these adjustments more efficient for the technician saving multiple firings staining, shading and repairing restorations.

Opaque Porcelain (Tru-Paque) The Tru-Paque opaque porcelain powder is a ceramic opaque spray porcelain intended to mask metal sub-structures. This provides a base layer for bonding additional translucent body porcelain layers of "Porcelain-Fused-to-Metal" (PFM) dental restorations. The purpose of opaque porcelains is to mask the dark color of metal sub-structures called "copings" used in porcelain-fused-to-metal constructed dental restorations, and to provide a layer to which translucent body porcelains are bonded. The Enamelite Tru-Paque is offered in an uncontaminated aerosolized form. As with the parent Leach and Dillon devices, the Tru-Paque opaque porcelain is applied on dental restorations in dental laboratories.

5. INTENDED USE

The Enamelite Porcelains Powders are aerosol devices intended to be used as spray applications of ceramic porcelains and glazes for dental restorations (crowns and bridges), which are produced in dental laboratories.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modified Enamelite Porcelain Powders and the predicate Leach and Dillon Porcelain Powders both include aerosol spray delivery systems to deliver the porcelain powders. Both the Nova Ceramic Spray Glaze and Tru-Paque opaque porcelain powders allow for consistent and controllable applications of porcelain powders. Both systems consist of highly refined aerosol delivery systems. The only significant difference between the predicate and the proposed devices is that Nova Ceramic Spray Glaze and Tru-Paque opaque porcelains are of a reduced particle size as compared to the larger sized porcelain

particles in the original Leach and Dillon product. As a result, the reduced particle size delivers a thinner more uniform coating resulting in more life-like dental restorations. Verification and Validation testing of the Enamelite devices was successfully performed and demonstrates that the modified devices function as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2003

Mr. Philip Pitts
Vice President, Products and Technology
Enamelite, LLC
1800 Business Park Drive, Suite 406
Clarksville, Tennessee 37040

Re: K030859
Trade/Device Name: Nova Ceramic Spray Glaze and Tru-Paque Opaque Porcelain
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: March 14, 2003
Received: March 18, 2003

Dear Mr. Pitts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

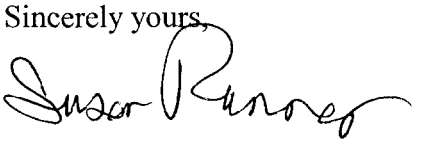
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030859

Device Name: Nova Ceramic Spray Glaze, Tru-Paque Opaque Porcelain

Indications For Use:

The Enamelite Porcelain Powders are aerosol devices intended to be used as spray applications of ceramic porcelains and glazes for dental restorations (crowns and bridges), which are produced in dental laboratories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Kevin Mulloy for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K030859